Supreme Court, U.S.
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No. 02-869

IN THE

Supreme Court of the United States

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,
Petitioner,

v.

RHONDA M. MEDOWS, Secretary, Agency for Health Care Administration of the State of Florida, and BOB SHARPE, Deputy Secretary of Medicaid, Agency for Health Care Administration of the State of Florida,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

REPLY BRIEF OF PETITIONER

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REPLY BRIEF OF PETITIONER

Florida does not dispute that the challenged Medicaid program has all of the attributes of a Medicaid drug formulary save one:

- The Florida statute creates a Medicaid Pharmaceutical and Therapeutics Committee comprised as specified in SSA § 1927(d)(4)(A), the provision of the federal Medicaid statute governing Medicaid drug formularies.
- The Florida statute directs the Committee to create a comprehensive list of prescription drugs covered by rebate agreements between manufacturers and the U.S. Secretary of Health and Human Services for which Medicaid coverage will be routinely provided, the essential characteristic of a Medicaid drug formulary. *See* SSA § 1927(d)(4)(B).
- The Florida statute provides for coverage through prior authorization of drugs excluded from this list, as required of all Medicaid drug formularies. *See* SSA § 1927(d)(4)(D).

Pet. at 6. The sole respect in which Florida's list does *not* resemble a state Medicaid formulary is its failure to satisfy SSA § 1927(d)(4)(C): drugs are excluded from Florida's list not on the basis of the written clinical determinations described in SSA § 1927(d)(4)(C), but on the basis of a manufacturer's refusal to pay the state a "supplemental" Medicaid rebate.

Florida also does not dispute that, on at least nineteen occasions, the Florida statute describes its undertaking as the establishment of a "formulary," Pet. at 5; that respondent Sharpe himself acknowledged that Florida has created a

"Medicaid drug formulary"[1]; and that AHCA sanitized its state plan amendment to eliminate the term "formulary" only after PhRMA brought this lawsuit and CMS told the state that it could not approve the Florida program as long as the state insisted on calling it a "formulary," Pet. at 10-11.

Nor, finally, does Florida dispute that the Eleventh Circuit's decision renders SSA § 1927(d)(4) a dead letter. As discussed in the petition, if a state may establish "preferred drug lists" otherwise indistinguishable from Medicaid formularies, but which exclude drugs on the basis of cost rather than the written clinical determinations described in SSA § 1927(d)(4)(C), states could achieve the effect of a Medicaid formulary free from the limitations on formularies that Congress imposed.

For the reasons stated in the petition, these facts warrant review of the Eleventh Circuit's decision. Florida, however, seeks to avoid review by asserting that PhRMA is not entitled to challenge the Florida statute as preempted; that this case does not raise an issue of national importance; that the United States in *Concannon* has not invited the Court to address the issue presented in the petition; and that nothing the Court may say in *Concannon* has implications here. None of these arguments for denying review is persuasive.

I. PhRMA May Challenge the Florida Statute as Preempted.

Florida is mistaken in asserting, BIO at 11, 13-15, that PhRMA may not challenge the Florida statute as preempted

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[1] Attach. 3 to Decl. of Russel A. Bantham at 3, *PhRMA v. Medows*, No. 4:01cv356-WS (N.D. Fla.) (filed Aug. 7, 2001).

under both the Supremacy Clause and 42 U.S.C. § 1983.[2]

This Court and lower federal courts routinely entertain preemption challenges to state laws asserted directly under the Supremacy Clause. *See, e.g., Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85 (1983); *Ray v. Atlantic Richfield Co.*, 435 U.S. 151 (1978); *City of Burbank v. Lockheed Air Terminal Inc.*, 411 U.S. 624 (1973). The Court is currently entertaining such a challenge in *Concannon*. Moreover, federal courts have consistently held that a party may challenge a state statute under the Supremacy Clause without relying on the existence of an enforceable right under the preempting federal statute.[3]

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[2] Contrary to Florida's assertion, BIO at 15, the district court ruled that PhRMA was entitled to challenge the Florida statute as preempted. (App. 50.) Florida did not challenge that ruling or otherwise raise the issue in the Eleventh Circuit and the Eleventh Circuit did not consider it. "Where issues are neither raised before nor considered by the Court of Appeals, this Court will not ordinarily consider them." *Penn. Dep't of Corr. v. Yeskey*, 524 U.S. 206, 212-13 (1998) (citation omitted). Moreover, even if Florida had raised the issue below, without filing a cross-petition Florida may not advance a claim that, if accepted, would require vacatur, rather than affirmance, of the Eleventh Circuit's judgment. *See, e.g., Northwest Airlines, Inc. v. County of Kent, Mich.*, 510 U.S. 355, 364-65 (1994) (barring, for failure to file a cross-petition, respondent's challenge to a court of appeals' finding of an implied right of action).

[3] *E.g., PhRMA v. Concannon*, 249 F.3d 66, 73 (1st Cir. 2001) (Where PhRMA raises "a preemption-based challenge under the Supremacy Clause. . . . , it is the interests protected by the Supremacy Clause, not by the preempting statute, that are at issue."), *cert. granted*, 122 S. Ct. 2657 (2002) (No. 01-188); *St. Thomas-St. John Hotel & Tourism Ass'n, Inc. v. Gov't of the United States Virgin Islands*, 218 F.3d 232, 241 (3d Cir. 2000) ("[A] state or (continued...)

Florida's reliance on cases such as *Golden State Transit Corp. v. City of Los Angeles*, 493 U.S. 103 (1989), is misplaced. BIO at 14. In these cases the Court held only that a party seeking relief under § 1983, or under a federal statute, must demonstrate an enforceable right under the statute. The Court's observations in those cases were not made in considering claims for relief directly under the Supremacy Clause. The Court did not hold, and has not held, that a party claiming a Supremacy Clause violation must demonstrate an enforceable right under the preempting federal law.

Florida is also incorrect in asserting that the Medicaid statute, and SSA § 1927(d)(4) in particular, "does not confer an enforceable right on pharmaceutical companies." BIO at 14. PhRMA, which asserts an injury resulting from state action in violation of the Medicaid statute, may seek relief under § 1983. *Cf. Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 509-10 (1990) (health care providers entitled to bring § 1983 action to challenge state reimbursement methods as violative of the Medicaid statute). The Medicaid statute is intended to benefit both Medicaid patients, as Florida recognizes, and pharmaceutical manufacturers. The statute promises manufacturers that Medicaid will cover their drugs if they agree to pay the rebates specified by Congress. The statute also limits, through its restrictions on formularies, a state's ability to restrict coverage of the drugs of participating manufacturers. SSA § 1927(d)(4)(B), (C). PhRMA's members have substantial interests in ensuring that their drugs are

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territorial law can be unenforceable as preempted by federal law even when the federal law secures no individual substantive rights for the party arguing preemption."); *W. Air Lines, Inc. v. Port Auth.*, 817 F.2d 222, 225 (2d Cir. 1987) ("A claim under the Supremacy Clause that a federal law preempts a state regulation is distinct from a claim for enforcement of that federal law.").

made available to Medicaid beneficiaries, and that Medicaid payments are made to the states on such drugs as are dispensed, in a manner consistent with the letter and purpose of the Medicaid drug program.

II. The United States Believes the Court Should Address the Question Presented by this Case.

As discussed in the petition, the United States in its *amicus* brief filed in *Concannon* (No. 01-188) has invited the Court to address the precise issue in this case. Pet. at 14-16. Florida responds that the United States did not invite the Court to address that issue but "dispatched summarily" PhRMA's position on the issue as lacking merit. BIO at 13. Florida's response, however, confuses two separate questions: whether the United States in *Concannon* has sought the Court's resolution of PhRMA's formulary claim; and whether the United States agrees with that claim. The United States in *Concannon* seeks to elicit more than a ruling on the precise statutory question presented in that case—whether the Medicaid statute bars states from using their Medicaid prior authorization powers for non-Medicaid purposes. The United States instead seeks to elicit a far broader ruling ratifying, among other things, its contention that state programs such as Florida's do not violate the formulary requirements of the federal statute. The Court should grant the instant petition to address that issue, which is presented here and not in *Concannon*.

III. The Issue Presented Is of National Importance.

1. Florida was only the first state to seek to reduce its Medicaid prescription drug costs by restricting Medicaid patients' access to drugs unless manufacturers agree to pay extra Medicaid rebates. Several other states have followed suit and more are waiting in the wings. *See* Pet. at 17-18 (citing programs in Michigan, Vermont, and New Mexico); Brief of Washington Legal Foundation et al. as *Amici* in Support of Petitioner at 7-8 (noting drug price-control pro-

grams in thirty states); Brief for the United States at 16 & n.3, *Concannon* (No. 01-188) (citing, *inter alia*, programs in Illinois, Louisiana, Minnesota, and West Virginia). Several of these programs, under the guise of "prior authorization programs," threaten to eviscerate the formulary safeguards contained in SSA § 1927(d)(4). The Eleventh Circuit's decision, if allowed to stand, will accelerate adoption of these programs nationwide, unraveling a critical provision of federal law.

2. This case thus presents "an important question of federal law that has not been, but should be, settled by this Court." Sup. Ct. R. 10(c). The Court has previously granted review in the absence of a circuit conflict where, as here, a federal preemption claim was rejected by the court below. *E.g.*, *Cal. Fed. Sav. & Loan Ass'n v. Guerra*, 479 U.S. 272 (1987) (whether Title VII preempted state law); *Mich. Canners & Freezers Ass'n, Inc. v. Agric. Mktg. & Bargaining Bd.*, 467 U.S. 461 (1984) (whether Agricultural Fair Practices Act preempted state law); *Pacific Gas & Elec. Co. v. State Energy Res. Conserv. & Dev. Comm'n*, 461 U.S. 190 (1983) (whether Atomic Energy Act preempted state law). Further development of the formulary issue through further litigation in the lower courts is not needed to illuminate the legal issues presented.[4]

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[4] Florida asserts that PhRMA's formulary argument is not of national importance because PhRMA did not raise it in the *Concannon* litigation. BIO at 12, 18. But the Maine program suffers from other glaring defects, including the state's use of its Medicaid powers for non-Medicaid purposes (which the United States agrees is unlawful) and its extraterritorial regulation in violation of the Commerce Clause. Neither of these features is present in the Florida program, the most salient defect of which is its violation of the formulary provision of the Medicaid statute.

3. The CMS letter of September 18, 2002, cited in BIO at 1, 16-17, counsels in favor of review, not against it. The very fact that CMS viewed the formulary issue presented by the Florida program as warranting a special communication to every State Medicaid Director demonstrates that this case raises an issue of national importance. CMS's decision to give these programs this green light supports PhRMA's argument that guidance from this Court is needed now.

That CMS disagrees with PhRMA does not mean that review is unwarranted. As Florida itself appears to recognize, CMS's view that the program is lawful (a view implicit in the agency's approval of Florida's program and explicit in the agency's letter of September 18, 2002) is not entitled to deference. *See* BIO at 17 (citing *Christensen v. Harris County*, 529 U.S. 576, 587 (2000) (rejecting Department of Labor's interpretation of the FLSA as "unpersuasive")). For the reasons given in the petition, CMS's views here are unpersuasive.

4. SSA § 1927(d)(1)(A) also does not save the Florida program. Although that provision permits "any drug" to be subjected to prior authorization, it does not, as Florida contends, provide that prior authorization may be imposed by a state irrespective of other substantive provisions of the federal Medicaid statute. Most importantly here, when a state establishes a Medicaid drug formulary, as Florida previously conceded that it has done, coverage may be restricted and prior authorization may be imposed *only* for the clinical reasons and in the manner provided in SSA § 1927(d)(4).[5]

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[5] Florida's account of the Medicaid statute's legislative history is selective and misleading. BIO at 4-7; *cf.* Pet. at 4-5, 23-26. Although Congress in 1990 did, as Florida asserts, BIO at 6, codify states' then-existing prior authorization practices, those prior practices consisted of applying prior authorization to an "ex-

(continued...)

Florida asserts that "there is a fundamental distinction under federal law between subjecting a drug to a prior authorization condition and excluding it from coverage altogether by excluding it from a restrictive formulary." BIO at 19. But Florida's premise is mistaken: drugs excluded from a Medicaid formulary are *not* excluded from coverage. SSA § 1927(d)(4)(D) specifies that a state *must* "permit[ ] coverage of a drug excluded from the formulary . . . pursuant to a prior authorization program that is consistent with [SSA § 1927(d)(5)]." And the initial exclusion from the formulary must itself have been for the clinical reasons set forth in SSA § 1927(d)(4)(C). It is Florida's failure to meet that condition that gives rise to this legal challenge.[6]

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tremely small" number of prescription drugs to "assure that the prescriptions dispensed are medically necessary." Pet. at 24-25 & n.17. But Congress simultaneously barred states from maintaining formularies, *see id.* at 24, and Congress obviously did not intend to allow states to accomplish, through prior authorization, the very thing it was simultaneously prohibiting them from accomplishing through formularies. *See id.* at 24-25. When Congress in 1993 revived state authority to maintain formularies, it prohibited them from excluding drugs except for clinical reasons. The imposition of that limitation would have been pointless if states could avoid it using their prior authorization power. *See id.* at 25-26.

[6] Florida asserts, without record citation or support, that "any drug that is at least as safe and effective as other drugs in its therapeutic class can be placed on the PDL irrespective of whether or not its manufacturer has agreed to pay a supplemental rebate to Florida." BIO at 9. The Eleventh Circuit did not so interpret the Florida regime (*see* App. 15); the Florida statute does not so provide, *see* Fla. Stat. § 409.912(38)(a)(37); and respondent Sharpe's statements are to the contrary: "For inclusion on the formulary, the law says a manufacturer has to meet that 10 (continued...)

The mere fact that a Florida physician purportedly can obtain prior authorization for a drug excluded from the state's list, if the physician is willing to spend enough time and jump though enough hoops to do so, *see* Pet. at 8-9, is irrelevant to the state's failure to make the clinical determinations required to justify exclusion of the drug from the list in the first place, or the resulting imposition of a prior authorization requirement. The statute nowhere suggests that the ease or difficulty of obtaining prior authorization has any bearing on the state's duty to perform the required clinical determinations. *See* SSA § 1927(d)(4). The United States itself has disavowed Florida's position, stating (in defending a challenged Michigan program) that the lawfulness of a prior authorization program does *not* turn on whether the state accedes to the request of the patient's physician.[7]

IV. At a Minimum, the Court Should Hold the Petition.

Florida's claim that this case and *Concannon* do not overlap, BIO at 28-29, is unpersuasive. The Eleventh Circuit itself recognized the overlap, commenting that the First Circuit in *Concannon* had adopted "this same interpretation of [ ] § 1396r-8(d)(5)," and that *Concannon* constituted "the only other appellate opinion that has addressed this issue." (App. 6; *see also id.* 23.)

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percent add-on requirement to be considered." Attach. 2 to Decl. of Russel A. Bantham at 64, *PhRMA v. Medows*, No. 4:01cv356-WS (N.D. Fla.) (filed Aug. 7, 2001).

[7] *See* Fed. Defs.' Mem. in Supp. of Mot. for Summ. J. and in Opp. to Pl.'s Mot. for Summ. J. at 7, *PhRMA v. Thompson*, No. 02-CV-1306 (D. D.C. filed June 28, 2002) (The "distinction [between programs where the physician has the final say and ones in which the physician does not] is not critical to the validity of a prior authorization program under the statute.").

Although *Concannon* does not raise the limitations imposed by the formulary requirements of SSA § 1927(d)(4), it does present one key question also raised by this case—whether a state's power to impose "prior authorization" requirements under SSA § 1927(d)(1) and (5) is unconstrained by other provisions of the statute. It is telling that the *amicus* brief submitted in *Concannon* by twenty-nine states explicitly raises that very question, arguing that "[t]here is no limitation in Medicaid on the number or identity of drugs subject to prior authorization [nor] . . . . any limitation on a State's motive or rationale in subjecting a drug to prior authorization." *Amicus* Brief of the States of Massachusetts et al. at 13, *Concannon* (No. 01-188). Whether SSA § 1927(d)(1) and (5) may be read in a vacuum, divorced from other substantive provisions of the federal Medicaid statute, and in a manner that renders those other provisions null, is a question presented by both cases.

The petition should at least be held for consideration pending the Court's disposition of *Concannon*.

CONCLUSION

For the foregoing reasons, as well as those set forth in the petition, *certiorari* should be granted. Alternatively, the petition should be held pending this Court's disposition of *Concannon*.

Respectfully submitted,

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